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PATENT
Y01-066AF/3763
\$IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF APPEALS

In re Application of: Machele Daniels
Serial No. 10/092,067
Filed: March 5, 2002
For: Intravenous Tubing Cuff

: Date: March 20, 2004
: Group Art Unit: 3763
: Examiner: Roz Ghafoorian

APPEAL BRIEF TRANSMITTAL LETTER

The Commissioner of Patents and Trademarks
Washington, D.C. 20231

Sir:

Enclosed is an Appeal Brief, in triplicate, for the above-identified patent application.

- ☐ Applicant petitions for an extension of time for month(s). If an additional extension of time is required, please consider this a petition therefore. Fee:
- ☐ An extension for month(s) has already been secured; the fee paid therefore of is deducted from the total fee due for the total months of extension now requested. Extension fee due with this request:
- ☒ Applicant believes that no extension of time is required. However, this conditional petition is being made to provide for the possibility that applicant has inadvertently overlooked the need for a petition for extension of time.
- ☐ The Appeal Brief Fee was paid in a prior appeal in which there was no decision on the merits by the Board of Appeals.
- ☒ The Appeal Brief Fee is enclosed herewith. Fee = \$165.00
- ☒ The total fee due is \$165.00.
- ☒ Address correspondence to the undersigned at 2095 Hwy. 211 NW, Suite 2-F, #356 Braselton, GA 30517.

This letter is submitted in triplicate.

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Respectfully submitted,

Kenneth W. Float
Reg. No. 29,233

Encls.

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PD- Y01-066

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Machel Daniels
Serial No. 10/092,067
Filed: March 5, 2002
For: Intravenous Tubing Cuff

: Date: March 20, 2004
: Group Art Unit: 3763
: Examiner: Roz Ghafoorian
: Batch No.:
: Patent No.:

**CERTIFICATE OF MAILING
UNDER 37 CFR 1.8**

The Commissioner of Patents and Trademarks
P. O. Box 1450
Alexandria, VA 22313-1450

Sir:

Identification of Transmitted Papers

Brief on Appeal in triplicate, Transmittal letter in triplicate, check in the amount of \$165.00, return receipt postcard

I hereby certify that the above-identified correspondence is being deposited with the United States Postal Service on March 20, 2004 with sufficient postage as first class mail, and is addressed to the Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450.

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PATENT
PD-Y01-066

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF APPEALS

Appeal No. _____

In re Application of: MACHELLE DANIELS

Serial No.: 10/092,067

Filed: March 5, 2002

For: INTRAVENOUS TUBING CUFF

APPELLANTS' BRIEF ON APPEAL

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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF APPEALS**

In re Application of: MACHELLE DANIELS : Date: March 20, 2004
Serial No.: 10/092,067 : Group Art Unit: 3763
Filed: March 5, 2002 :
For: INTRAVENOUS TUBING CUFF : Examiner: Roz Ghafoorian

APPELLANT'S BRIEF ON APPEAL

Commissioner of Patents and Trademarks
Washington, D. C. 20231

Sir:

This is Appellants' brief on appeal from the decision of the Examiner in the Office Action dated October 23, 2003 finally rejecting Claims 1-14 in the above-identified patent application. This brief is submitted in accordance with the provisions of 37 C.F.R. §1.192.

REAL PARTY IN INTEREST

The real party in interest is the inventor, Machelles Daniels.

RELATED APPEALS AND INTERFERENCES

There are no other appeals or interferences known to appellants, appellant's legal representative, or the assignee which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

STATUS OF CLAIMS

Claims 1-19 are currently pending in this application and were finally rejected in the Office Action dated October 23, 2003. Appellant appeals from this final rejection.

STATUS OF AMENDMENTS

With regard to the status of amendments, no claim amendments were made in response to the final Office Action dated October 23, 2003. The Claims as they currently stand are presented in the Appendix.

SUMMARY OF INVENTION

The present invention provides for a single-patient disposable noninvasive intravenous (I.V.) tubing cuff 10 for use in securing an I.V. tube 23, or the like, to a patient. The disposable I.V. tubing cuff 10 is removably secured to a patient's limb 22, such as a wrist, arm or leg, and

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holds the I.V. tube 23 without sliding on the patient's limb 22. The disposable I.V. tubing cuff 10 provides for an improvement over the use of adhesive tape to secure I.V. tubes 23 to a patient's limb.

The disposable I.V. tubing cuff 10 is a disposable medical device having a self-adjusting intravenous tubing cuff configuration. The device is constructed using hypo-allergenic components, secures and stabilizes I.V. tubing to the patient's limb 22 without adhesive material. The device thus preserves skin integrity and prevents dislodging of the I.V. tubing.

An exemplary disposable I.V. cuff 10 comprises a strip or layer of soft, porous, cloth-like material 11. A thin strip or layer of soft "non-skid" porous foam rubber 12 is secured to one side of the layer of porous, cloth-like material 11. The layer of soft porous foam rubber 12 touches the patient's skin.

The porous nature of both the cloth-like material 11 and the foam rubber 12 permit the cuff 10 to breath and allow oxygen to get to the patient's skin. The layer of foam rubber 12 prevents the cuff 10 from rolling around the limb 22 or sliding up and down the limb 22.

Opposite ends of the cuff 10 are secured together using hook and loop materials 13, 14, such as Velcro™ material, for example. A piece or layer of hook material 13 having hooks thereon is attached or secured to one end of the porous, cloth-like material 11 on the same side and adjacent to the layer of porous, foam material 12.

A layer of loop material 14 is attached or secured to the opposite end of the porous, cloth-like material 11 on a side that is opposite to the hook material 13. When the cuff 10 is wrapped around the patient's limb 22, hooks of the hook material 13 come into contact with and engage loops of the loop material 14 to hold the two ends of the cuff 10 together.

A bendable or foldable adhesive layer 15 is attached or secured to the porous, cloth-like material 11 on the same side as the layer of loop material 14. The adhesive layer 15 preferably has a protective layer 16 that covers adhesive which is removed to expose the adhesive. An I.V. is laid on the exposed adhesive and the adhesive layer 15 is wrapped around the I.V. to secure it to the cuff 10.

ISSUES

The first issue in this appeal is whether Claims 1, 2, 7, 8, 11, 12 and 14 are anticipated by US Patent No. 3,826,254 issued to Mellor. The second issue in this appeal is whether Claims 4 and 6 are unpatentable over US Patent No. 3,826,254 issued to Mellor in view of US Patent No. 5,342,317 issued to Claywell. The third issue in this appeal is whether Claims 5, 9 and 10 are unpatentable over US Patent No. 3,826,254 issued to Mellor in view of US Patent No. 5,879,335 issued to Martinez et al.

GROUPING OF CLAIMS

With regard to the specific grounds of rejection that are in issue, it is respectfully submitted that Claims 1-14 stand or fall together.

ARGUMENT

The first issue in this appeal is whether Claims 1, 2, 7, 8, 11, 12 and 14 are anticipated by US Patent No. 3,826,254 issued to Mellor. It is respectfully submitted that the present invention is not anticipated by, nor is it obvious in view of the Mellor patent.

The Examiner's position as stated in the final Office Action is that "Mellor teaches a tubing cuff for securing a tube with a layer of porous material a layer of layer of foam rubber secured to one side of the layer of porous; a reclosable fastener for securing distal needs of the cuff and a bendable adhesive layer having an adhesive attaché do the porous material." It is respectfully submitted that the Examiner's rejection is in error.

The Mellor patent discloses in the Summary of the Invention section that "the appliance comprises a lengthwise elongated pad having first and second elongated sections, the second section defining a flap extending lengthwise beyond the first section to be folded back over one side of the first section and over the needle, catheter or butterfly device oriented to extend crosswise of the pad; first pressure sensitive adhesive means on the opposite side of the first section to adhere the first section to a patient's body; and second pressure sensitive adhesive means on the pad to adhere the flap to the pad first section and to be adherent to the retained device oriented as defined. Also, peel-off backer strip means may typically be applied to the first and second pressure sensitive adhesive means, as will appear. As a result, rapid and firm retention of the needle or catheter to the patient's body is enabled by means of a single appliance or pad, with the danger of undesirable needle or catheter inadvertent rotation or disattachment substantially eliminated."

It is therefore respectfully submitted that the Mellor pad is constructed as a single piece of material that is folded back upon itself to hold a needle, catheter or butterfly device. The Mellor patent discloses in column 2, lines 19-20 that the "pad may consist, for example, of a layer of porous plastic foam, as for example polyurethane". A "first pressure sensitive adhesive means" is used to adhere the pad to a patient's body. A "second pressure sensitive means" is used to adhere the folded flap (second section) to the first section.

Claim 1 recites:

1. A tubing cuff for securing a tube to a limb of a patient, comprising:
 - a layer of porous, cloth-like material;
 - a layer of porous foam rubber secured to one side of the layer of porous, cloth-like material;
 - a reclosable fastener for securing distal ends of the cuff together; and
 - a bendable adhesive layer having an adhesive surface attached to the porous, cloth-like material on a side opposite to the layer of porous foam rubber.

With regard to Claims 1, it is respectfully submitted that there is no disclosure or suggestion in the Mellor patent regarding the use of two independent layers of different material to form the appliance. The Mellor patent clearly discloses that the appliance is made of a single layer of material ("a layer of porous plastic foam") that is folded back upon itself to secure a needle, etc. The present invention is made of two layers comprises a layer of porous foam rubber secured to one side of a layer of porous, cloth-like material. [Emphasis added]

It is respectfully submitted that there is no disclosure or suggestion in the Mellor patent regarding the use of "cloth-like material" in the appliance. The term "cloth" is not used in the Mellor patent.

There is no disclosure or suggestion in the Mellor patent regarding the use of "porous foam rubber" in the appliance. While the Mellor patent states that the "pad may consist, for example, of a layer of porous plastic foam, as for example polyurethane", it is respectfully submitted that this is not a disclosure or suggestion of the use of "porous foam rubber". Polyurethane is not a porous foam rubber material. Furthermore, the term "rubber" is not used in the Mellor patent.

Furthermore, the Mellor article is secured to a patient's body using adhesive. This is clearly not the case with the present invention, which secures and stabilizes I.V. tubing to a patient's limb without the use of adhesive material, as is stated in the Summary of the Invention section, for example, of the present application.

In view of the above discussion, and with specific regard to Claim 1, it is respectfully submitted that the Mellor patent does not disclose or suggest a tubing cuff comprising "a layer of porous, cloth-like material" and "a layer of porous foam rubber secured to one side of the layer of porous, cloth-like material", as is recited in Claim 1.

Therefore, it is respectfully submitted that the invention recited in Claim 1 is not disclosed or suggested by the Mellor patent, and is therefore not anticipated by, nor is it obvious in view of, the Mellor patent. Reversal of the Examiner's rejection of Claim 1 is respectfully requested.

With regard to Claim 2, it is respectfully submitted that the Mellor patent does not disclose or suggest the use of a microporous film layer as the primary strap layer. The terms "microporous" or "microporous film" are not used in the Mellor patent. Therefore, it is respectfully submitted that the Mellor patent does not disclose or suggest that "the layer of porous, cloth-like material comprises microporous film", as is recited in Claim 2.

With regard to Claim 7, it is respectfully submitted that the Mellor patent does not disclose or suggest that "the layer of porous foam rubber comprises non-skid porous foam rubber", as is recited in Claim 7. These terms are not used in the Mellor patent.

With regard to Claims 8, 11 and 12, it is respectfully submitted that the Mellor patent does not disclose or suggest the use of a reclosable fastener that comprises "hook and loop materials". There are no hook and loop materials discussed in the Mellor patent. The terms "hook" and "loop" are not used in the Mellor patent.

With regard to Claim 14, it is respectfully submitted that the Mellor patent does not disclose or suggest that a "layer of porous foam rubber is placed against the patient's limb and secured by the reclosable fastener." The Mellor patent clearly discloses that an adhesive layer is used to secure the elongated pad to the patient's body. The present invention expressly teaches away from the use of adhesive material to secure the tubing cuff to the body.

Dependent Claims 2, 7, 8, 11, 12 and 14 are also considered patentable based upon their dependence from allowable Claim 5. Therefore, it is respectfully submitted that the inventions recited in Claims 2, 7, 8, 11, 12 and 14 are not disclosed or suggested by the Mellor patent, and that the inventions in Claims 2, 7, 8, 11, 12 and 14 are not anticipated by, nor they obvious in view of the Mellor patent. Therefore, reversal of the Examiner's rejection of Claims 2, 7, 8, 11, 12 and 14 is respectfully requested.

Claims 4 and 6 were rejected under 35 U.S.C. § 103(a) as being unpatentable over US Patent No. 3,826,254 issued to Mellor in view of US Patent No. 5,342,317 issued to Claywell. The Examiner admitted that the Mellor patent does not disclose a hypoallergenic porous layer. The Claywell patent is cited by the Examiner as teaching a tubing cuff with a hypoallergenic layer, which the Examiner concluded could have been used in the Mellor appliance.

It is respectfully submitted that the Mellor and Claywell patents, taken singly or together, do not disclose or suggest the invention recited in Claim 1, for the reasons argued above. Therefore, it is respectfully submitted that the Mellor and Claywell patents, taken singly or together, do not disclose or suggest the inventions recited in Claims 4 and 6.

Furthermore, dependent Claims 4 and 6 are considered patentable based upon their dependence from allowable Claim 1. Therefore, it is respectfully submitted that the inventions recited in Claims 4 and 6 are not obvious in view of the Mellor or Claywell patents, taken singly or together. Reversal of the Examiner's rejection of Claims 4 and 6 is respectfully requested.

Claims 5, 9 and 10 were rejected under 35 U.S.C. § 103(a) as being unpatentable over US Patent No. 3,826,254 issued to Mellor in view of US Patent No. 5,879,335 to Martinez et al. The Examiner admitted that the Mellor patent does not teach the use of a woven loop with a durable backing layer. The Martinez patent is cited by the Examiner as teaching a woven loop with a durable backing layer, which the Examiner concluded could have been used in the Mellor device.

It is respectfully submitted that the Mellor and Martinez et al. patents, taken singly or together, do not disclose or suggest the invention recited in Claim 1, for the reasons argued above. Therefore, it is respectfully submitted that the Mellor and Martinez et al. patents, taken singly or together, do not disclose or suggest the inventions recited in Claims 5, 9 and 10.

With regard to Claim 5, it is respectfully submitted that the Mellor and Martinez et al. patents, taken singly or together, do not disclose or suggest a tubing cuff that comprises a laminate of microporous film and a polypropylene nonwoven material. These terms are not used in the cited patents.

With regard to Claims 9 and 10, it is respectfully submitted that there is no specific teaching contained in the Mellor and Martinez et al. patents that would suggest their combination to add hook and loop materials to the Mellor appliance. It is respectfully submitted that the Examiner has used inappropriate hindsight reconstruction, using the teachings of the cited references in light of Applicant's teachings to arrive at the inventions recited in Claims 9 and 10.

In addition, dependent Claims 5, 9 and 10 are considered patentable based upon their dependence from allowable Claim 1. Therefore, it is respectfully submitted that Claims 9 and 10 are not obvious in view of the Mellor and Martinez et al. patents, taken singly or together. In view of the above, reversal of the Examiner's rejection of Claims 5, 9 and 10 is respectfully requested.

It is noted that Claim 3 was not specifically rejected by the Examiner in the final Office Action. In the Office Action mailed April 25, 2003, the Examiner cited US Patent Publication No. 2002/0165495 of Bird et al. in combination with US Patent No. 5,529,062 issued to Byrd as disclosing the invention recited in Claim 3. It is respectfully submitted that the combined teachings of these references, taken singly or together, do not disclose or suggest the invention recited in Claim 3, and not without the use of hindsight reconstruction.

With regard to this rejection, the Examiner admitted that "Bird teaches the invention except for the layer of porous material comprising polypropylene material. The Examiner stated that "Byrd teaches a layer of porous polypropylene material, which the Examiner concluded could have been used in the Bird et al. device.

It is respectfully submitted that the Bird et al. reference and Byrd patent, taken singly or together, do not disclose or suggest the invention recited in Claim 1, in particular because the Examiner did not cite these references in the final Office Action, but instead cited the newly found Mellor reference. Furthermore, it is respectfully submitted that the Bird et al. document does not disclose or suggest the use of microporous film. The terms "microporous" or "microporous film" are not used in the Bird et al. document. As is stated in the Bird et al. document, the primary strap is made of an "elastic woven, knit, or webbing material".

It is stated in the Byrd patent at column 3, in the third full paragraph of the "Best Mode" section of the specification, that the "straps 24 are fabricated of a soft pliable material, such as a spun-bond polypropylene, having a surface 25 covered with a cellophane or plastic coating". The use of such a material having spun-bond polypropylene covered with a cellophane or plastic is not compatible with the teachings of the Bird et al. reference. Therefore, it is respectfully submitted that combining the teachings of the Bird et al. and Byrd references improperly extends the teachings of the Bird et al. document beyond its scope, which amounts to hindsight reconstruction.

In view of the above, it is respectfully submitted that the Bird et al. and Byrd references, taken singly or together, do not disclose or suggest the inventions recited in Claims 3 and 5. Dependent Claim 3 is also considered patentable based upon its dependence from allowable

Claim 1. Therefore, it is respectfully submitted that Claim 3 is not obvious in view of the Mellor and Byrd patents, taken singly or together.

It is respectfully submitted that issuance of the final Office Action was premature, in that Applicant did not necessitate any new grounds of rejection as argued by the Examiner. The Mellor patent does not disclose or suggest the use of a two layer tubing cuff, it is a single layer. The amendments made by Applicant in the response to the Office Action mailed April 25, 2003 were minor in scope and did not change the nature or extent of the search required by the Examiner. It is respectfully submitted that the Examiner did not find the Mellor patent during the initial search. It is respectfully submitted that Applicant has been penalized for this. It is respectfully submitted that Applicant did not necessitate any new grounds of rejection as stated by the Examiner.

In view of the above, it is respectfully submitted that Claims 1-14 are not anticipated by, nor are they obvious in view of, the cited references, taken singly or together, and are therefore patentable. Therefore, it is respectfully submitted that the rejection of Claims 1-14 by the Examiner was erroneous, and reversal of the Examiner's decision is respectfully requested.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Kenneth W. Float', written over a horizontal line.

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Registration No. 29,233

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APPENDIX

Claims 1-14 presented below are pending in this application.

1. A tubing cuff for securing a tube to a limb of a patient, comprising:
a layer of porous, cloth-like material;
a layer of porous foam rubber secured to one side of the layer of porous, cloth-like material;
5 a reclosable fastener for securing distal ends of the cuff together; and
a bendable adhesive layer having an adhesive surface attached to the porous, cloth-like material on a side opposite to the layer of porous foam rubber.
2. The tubing cuff recited in Claim 1 wherein the layer of porous, cloth-like material comprises microporous film.
3. The tubing cuff recited in Claim 2 wherein the microporous film comprises polypropylene material.
4. The tubing cuff recited in Claim 2 wherein the microporous film is hypoallergenic.
5. The tubing cuff recited in Claim 2 wherein the microporous film comprises a laminate of microporous film and a polypropylene nonwoven material.
6. The tubing cuff recited in Claim 1 wherein the layer of porous, cloth-like material is hypoallergenic.
7. The tubing cuff recited in Claim 1 wherein the layer of porous foam rubber comprises non-skid porous foam rubber.
8. The tubing cuff recited in Claim 1 wherein the reclosable fastener comprises hook and loop materials.
9. The tubing cuff recited in Claim 8 wherein the hook and loop materials comprise a nonwoven loop with a film backing.
10. The tubing cuff recited in Claim 8 wherein the hooks are attached to a durable backing layer.

11. The tubing cuff recited in Claim 8 wherein the reclosable fastener comprises knitted loop and hook materials.

12. The tubing cuff recited in Claim 1 wherein the reclosable fastener comprises a layer of hook material having hooks thereon attached to one end of the porous, cloth-like material on the same side and adjacent to the layer of porous foam rubber; and a layer of loop material attached to an opposite end of the porous, cloth-like material on a side that is opposite to the hook material.

13. The tubing cuff recited in Claim 1 wherein the adhesive layer has a protective layer that covers adhesive material and which is removed to expose the adhesive material of the adhesive layer.

14. The tubing cuff recited in Claim 1 wherein the layer of porous foam rubber is placed against the patient's limb and secured by the reclosable fastener, and wherein a tube is laid on exposed adhesive of the bendable adhesive layer, which bendable adhesive layer is wrapped around the tube to secure it to the cuff.